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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/528,241

12/02/2005

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14506-49286

4113

24728 7590 08/25/2009
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EXAMINER

LIPITZ, JEFFREY BRIAN

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

08/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,241	Applicant(s) LIN ET AL.	
	Examiner DR. JEFFREY B. LIPITZ	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/17/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/15/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-24, drawn to methods of identifying tissue, classified in class 600, subclass 317.

Group II, claim(s) 25-46, drawn to a medical tissue ablation system, classified in class 606, subclass 46.

Groups I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the processes as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice other and materially different processes. (MPEP § 806.05(e)). In this case the processes as claimed can be practiced by another and materially different apparatus. The process does not require a tubular member or an optical fiber. Instead, the processes could be practiced with an implantable device of any shape that contains light emitting diodes as light sources. The optical signals from the reflected light could be captured by photodetectors embedded in the device, and sent by telemetry to a processor for analysis.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (b) the inventions require a different field of search (for example, searching different electronic resources or employing different search queries);
- (c) the prior art applicable to one invention would not likely be applicable to another invention;
- (d) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after

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the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Tin Xia on June 25, 2009 a provisional election was made without traverse to prosecute the invention of group II, claims 25-46. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are

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subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the shading in Figures 1, 2, 8, 9a, 9b, 10-14, 16, 17a and 17b renders the illustrations unclear. Applicant is advised to employ the services of a

competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

The drawings are objected to because Figures 1, 2, 8, 9a, 9b, 10-16, 17a and 17b do not have indicia indicative of the function of many of the elements of the drawings.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25-31 and 33-35, 37-39 and 41-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Balbierz et al. (20020026188), hereinafter Balbierz.

Regarding claim 25, Balbierz teaches a tissue diagnostic system (Paragraph [0002]) having a tubular or elongated member or introducer (12) with one or more resilient members or electrodes (18a-e) extending through the introducer (12) that are individually deployable and coupled to an ablative source (20; Paragraphs [0047] and [0088]; Figures 1, 2, 7, 20 and 23). Balbierz also teaches a light detecting member or first optical fiber (22md; Paragraph [0058]) encased in a first tubular needle or non-energy delivery resilient member (18; Paragraph [0055]; Figure 8) extending through the introducer (12) that can deliver light to a spectrometer or spectrophotometer or optical measurement device, which produces spectral signals (19) at its proximal end and collect light from tissue at its distal end (Paragraphs [0057]-[0061]; Figure 4).

Regarding claim 26, Balbierz teaches a light source (17 or 317; Paragraph [0060]) coupled to the proximal end of a second optical fiber (22me; Paragraph [0060]). The fiber extends through the tubular member (12) and has a distal end next to the ablation site (Paragraphs [0051]-[0059]; Figures 2, 4, 7-9 and 12-14).

Regarding claim 27, Balbierz teaches a light source emitting ultraviolet light capable of generating fluorescence in the tissue (Paragraph [0072]).

Regarding claims 28-31, Balbierz teaches that the light source could be a laser or a xenon bulb emitting light in a range of 300-850 nm, which includes the ranges claimed by Applicant, or a white light source (Paragraph [0060] and [0070]). The interaction of light with the tissue is nothing more than the intended outcome of shining light on the tissue. It does not further modify any element of the invention.

Regarding claims 33 and 37, Balbierz teaches that the first and second optical fibers (22md and 22me) could extend through the first tubular needle or resilient member (18; Paragraphs [0055] and [0058]; Figures 8a-c). In a second embodiment of Balbierz, second optical fiber (22me) is encased in a second hollow needle (18e; Paragraph [0058]; Figure 8d).

Regarding claims 34 and 38, Balbierz teaches that the tubular needles (18e) are coupled with an RF ablation power source (Paragraphs [0089] and [0091]).

Regarding claims 35 and 39, Balbierz teaches an insulator or insulating cover (36) on the distal end of the needle (18; Paragraphs [0091], [0094] and [0095]; Figures 22 and 25-28). Examiner interprets all electrical insulators as thermal insulators.

Regarding claims 41-46, these claims recite substantially similar limitations to claims 27-31, rejected supra.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 32 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz as applied to claims 25, 26, 30, 31 and 37, above, and further in view of Adair (4782819).

Regarding claims 32 and 46, Balbierz does NOT teach using a halogen lamp as the light source. Attention is directed to Adair who teaches an optical catheter that can use a halogen lamp as the light source (Title, Column 9, Lines 1-5). It would have been obvious to use the lamp of Adair with the invention of Balbeirz because halogen lamps provide visible light which is used to attain spectral measurements and provide illumination.

Claims 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz as applied to claims 25, 34 and 37 above, in combination with Hayes et al. (US 4967745), hereinafter Hayes.

Regarding claims 36 and 40, Balbierz does NOT teach transparent covers for the distal ends of the tubular needles. Attention is directed to Hayes who teaches a multi-fiber plug for a laser catheter (Abstract). Hayes teaches using a tubular member or catheter body (16), a spectrometer (64; Column 24, Lines 31-52), an optical fiber (20a-c), and a transparent optical shield or cover (12) at the distal end of the device (Column 8, Lines 5-15; Column 4, Lines 40-55; Column 7, Lines 58-61; Figure 1). Hayes does NOT teach electrodes. It would have been obvious to include the transparent shield of Hayes with the invention of Balbierz because including a transparent cover will allow

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light to be emitted and collected by the optical fibers enclosed in the needles, but also protect the fibers from damage and obstruction by tissue during ablation, or in the alternative it would have been obvious to include the electrodes of Balbierz with the invention of Hayes, because electrodes are also used for the removal of vascular obstructions (Hayes: Column 1, Lines 10-14).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Leo (20060200049) teaches a medical apparatus having an optical fiber load sensing capability. Morris (20090076497) teaches a tissue surface treatment apparatus and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/david shay/
Primary Examiner, Art Unit 3769